

**PROTOCOL SYNOPSIS:**

Title: A Phase I/II Study of an Antitumor Vaccination Using  $\alpha(1, 3)$  Galactosyltransferase ( $\alpha(1,3)$ GT) Expressing Allogeneic Tumor Cells in Patients with Recurrent or Refractory Non-Small Cell Lung Cancer.

Primary Objective: To determine the safety and response rate of the administration of HyperAcute™ Lung (HAL) Cancer Vaccine cells by injection into patients with recurrent or refractory non-small cell lung carcinoma.

Secondary Objective: To conduct correlative scientific studies of patient samples to determine the mechanism of any observed antitumor effect. In these studies human humoral and cellular immune responses to HAL cells will be evaluated.

Population: Patients with refractory or recurrent non-small cell lung carcinoma (NSCLC).

Sample size: Maximum 52 patients (if each Phase I cohort is required to be expanded to the maximum 6 patients it will be 52).

Investigational Drug: HyperAcute™ Lung Cancer Vaccine consisting of three equal cell doses of allogeneic lung cancer cell lines engineered to express the murine  $\alpha(1,3)$ GT gene.

Dosage Treatment: Cells will be injected intradermally every four weeks for four cycles. Dosage will vary from a total of  $3 \times 10^6$  to  $1 \times 10^8$  HyperAcute™ Lung Cancer Vaccine cells administered.

Clinical Endpoints: Phase I- Development of grade >3 adverse events related to the HyperAcute™ Lung Cancer Vaccine. Phase II- Tumor response, and overall survival.